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Linda C. Tiefel, CEO

• Central Office ♦  
280.5 Kipling Street  
Lakewood, Colorado 80215  
303-233-1223  
1-800-258-5250  
FAX 303-233-8755  
Email: LOCbones@aol.com

♦ North Office ♦  
93.51 Grant Street  
Suite 490  
Thornton, Colorado 80229  
303-452-8001  
FAX 303-452-1167

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Dockets Management Branch (HFA-305)

ATTN: Docket #97N-484S  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Dear Sirs:

This letter is in regards to further regulating bone allograft for use in orthopaedic surgery. It has come to my attention that there is a move to impose further regulation on allograft bone, especially in relation to spine fusion surgery.

Allograft bone has been used in spine fusions for decades successfully when used in the proper patients and proper indications. Further regulation of this material would add additional expense and is not justified, since this is a product which has been used successfully without any significant increased risk or complications over other available techniques for many years. I would therefore recommend that you not impose further regulation in the processing or use of bone allograft.

Sincerely,

James S. Gebhard, M.D.  
JSG/wld/10741

Signature stamped  
to avoid delay in mailing

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Duane G. Messner, M.D.  
Courtney W. Brown, M.D.  
David H. Donaldson, M.D.  
Thomas G. Friermood, M.D.  
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Mitchell D. Seemann, M.D.  
James S. Gebhard, M.D.  
Bharat M. Desai, M.D.  
Ranee M. Shenoi, M.D.  
Peter N. Lammens, M.D.  
Douglas C. Wong, M.D.

1805 Kipling Street  
Lakewood, Colorado 80215

9351 Grant Street #490  
Thornton, Colorado 80229



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SU30 Fishers Lane #1001  
Rockville, MD 20852